DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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Silver Spring, MD 20993-0002

January 15, 2015

Philips Medical Systems
Theresa Poole
Regulatory Affairs Specialist
3000 Minuteman Road
Andover, Massachusetts 01810

Re: K142935
Trade/Device Name: CareEvent
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor (Including Cardiotachometer And Rate Alarm)
Regulatory Class: Class II
Product Code: MSX
Dated: December 15, 2014
Received: December 16, 2014

Dear Theresa Poole,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in

the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Melissa A. Torres -S

For Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): _____

Device Name: ___CareEvent

Indications for Use:

The intended use of the CareEvent solution is to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). The product can route all of subsets of this information to selective remote devices such as pagers, phones, or marquees. Receipt of alarm messages or events by the external device, is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

The CareEvent mobile application software provides healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). Receipt of alarm messages or events by the external mobile device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

Prescription Use ___Yes____ (Part 21 CFR 801 Subpart D)	AND/OR	Over-The-Counter Use __No_____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

This summary of 510(k) safety and effectiveness information is submitted in accordance with the requirements of the Safe Medical Devices Act of 1990 and 21 CFR §807.92.

The submitter of this premarket notification is:
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This summary was prepared on 15 January 2015.

The name of this device is the CareEvent.

Device Description
The CareEvent solution is designed to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events).

Classification names are as follows:

Device Panel	Classification	ProCode	Description
Panel 74 Cardiovascular	§870.2300, II	MSX	System, Network and Communication, Physiological Monitors

The CareEvent solution is substantially equivalent to the previously cleared predicate IntelliSphere Event Management (K102974).

Intended Use
The intended use of the CareEvent solution is to provide healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). The product can route all of subsets of this information to selective remote devices such as pagers, phones, or marquees. Receipt of alarm messages or events by the external device, is not confirmed and delivery to the end device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.

The CareEvent mobile application software provides healthcare professionals with supplemental information about patient alarms, technical alarms, nurse call alarms and system information messages (events). Receipt of alarm messages or events by the external mobile device is not guaranteed. The primary alarm notification is the device producing the alarm or event. This

product line is not intended to provide real-time information, nor is it a source of patient alarms, nor is it a replacement for alarming devices.
The device has the same Indications for Use and Intended Use as the legally marketed predicate device.

The technological characteristics are the same as the legally marketed predicate device.

Software changes have been made to accommodate the communication to the CareEvent mobile application accessory.

Verification, validation, and testing activities establish the performance, functionality, and reliability characteristics of the new device with respect to the predicate. Testing involved system level tests, performance tests, and safety testing from hazard analysis. Pass/Fail criteria were based on the specifications cleared for the predicate device and test results showed substantial equivalence. The results demonstrate that the device meets all defined reliability requirements and performance claims.